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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,184	11/25/2003	Jeffrey O. Phillips	03207556	7922

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MAYER BROWN LLP
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CHICAGO, IL 60690

EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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02/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/722,184	Applicant(s) PHILLIPS, JEFFREY O.	
	Examiner Celia Chang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 151-153, 156, 160, 161, 167-170 and 174-210 is/are pending in the application.
- 4a) Of the above claim(s) 158, 171-173 and 211-272 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 151-153, 156, 160, 161, 167-170 and 174-210 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application is a RCE of SN 10/722,184.

Claims 151-153, 156, 160-161, 167-170 and 174-210 are currently pending. Claims 158, 171-173, 211-272 stayed withdrawn from consideration.

2. Claim 152 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is confusing that the omeprazole is esomeprazole. Please note that omeprazole and esomeprazole are different material. Since esomeprazole is the isomer of omeprazole, it is recommended that the term omeprazole isomer be used.

3. Claims 151-153, 156, 160-161, 167-170, 174-210 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is well recognized in the art that blood concentration of a drug after an oral dose is a dose dependent process. The specification provided blood concentration measurements using single 40 mg omeprazole in 20 mEq sodium bicarbonate. Such results can support the serum profile for a single 40 mg omeprazole dosing but not the instantly claimed scope wherein a 0.05mEq-5mEq buffer per mg omeprazole "composition" is able to achieve a 0.1 µg/ml within 30 minutes of dosing. There is no evidence in the record that a composition meeting the ratio requirement without at least a therapeutically effective dose of omeprazole can achieve such a blood level. In addition, there is no evidence in the record that such blood level can be obtained when the drug to buffering agent ratio varied beyond the 20-40 mg omeprazole single dosage composition with the ratio of 0.2mEq-5mEq per 2 mg of omeprazole using bicarbonate as the buffering agent. Please note, the agents as listed in claim 161 all have different pH, ionic

strength, buffering capacity, there is no evidence that all such broad range of basic compounds can form buffer (see Bull p. 103). Nor was there any support that the wide varieties of basic agent of claim 161 would all function in analogous manner in providing serum absorption or omeprazole stabilizing effect with the 0.2mEq-5mEq per 2 mg of omeprazole parameter.

4. Claims 151-153, 156, 160-161, 167-170 and 174-210 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,489,364. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant more limited scope is *fully* embraced by the issued claims.

Claims 151-153, 156, 160-161, 167-170 and 174-210 are rejected as being unpatentable over claims 18-56 of US 6,489,364 or claims 1-51 of US 6,699,885 or the claims are provisionally rejected over the copending claims 24-25, 32-36, 77-88, 90-100, 103-110 of SN 10/641,732, on the ground of nonstatutory obviousness-type double patenting. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to material being used in the issued claims or copending claims. The material and method of using the exact same material should be bind together to prevent unreasonable multiple harassment based on the decision of *In re Ochai*. Please note that no restriction between the material and method of using the identical material was made. Therefore were the claims presented in a single application, they would be joined in issuance.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.


Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jan. 24, 2008


Celia Chang
Primary Examiner
Art Unit 1625